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To the Graduate Council:

I am submitting herewith a thesis written by Jeffrey Scott Rogers entitled "Instrumentation Development For Assessing The Environment Inside Shipping Containers Of Pancreatic Islets During Air Transportation." I have examined the final electronic copy of this thesis for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Master of Science, with a major in Mechanical Engineering.

Basil Antar, Major Professor

We have read this thesis and recommend its acceptance:

Frank Collins, Roy Schulz

Accepted for the Council: Carolyn R. Hodges

Vice Provost and Dean of the Graduate School

(Original signatures are on file with official student records.)



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Accepted for the Council:

Anne Mayhew Vice Chancellor and Dean of Graduate Studies

(Original signatures are on file with official student records.)



INSTRUMENTATION DEVELOPMENT FOR ASSESSING THE ENVIRONMENT INSIDE SHIPPING CONTAINERS OF PANCREATIC ISLETS DURING AIR TRANSPORTATION

A Thesis Presented for the Master of Science Degree The University of Tennessee, Knoxville

> Jeffrey Scott Rogers May 2004



For my parents



ACKNOWLEDGEMENTS

I wish to thank all those who helped me complete my Master of Science degree in Mechanical Engineering. I would like to thank Dr. Basil Antar and Dr. Frank Collins for their guidance and effort in making me familiar with experimental testing research. I would like to thank Mike Leigh for his instrumentation support and troubleshooting. I would also like to thank Dr. Roy Schulz for serving on my committee.

Finally, I would like to thank my family and friends, whose encouragement helped me to remain focused and persevere.



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ABSTRACT

This study was conducted to obtain information on the effect of altitude on the internal environment of shipping containers for pancreatic islet cells being transported by commercial aircraft. Previous experience has shown that islet cell counts decrease after the islet cells have been transported by air and received at their point of destination.

A data acquisition system was designed to gather fundamental data for use in the analysis of the effects of the environment inside the containers holding the pancreatic islet cell samples being shipped by either ground or air transport, or both. A test apparatus, which fits the existing islet containers, was constructed to sense temperature, pressure, and the presence of dissolved gases in the islet container, because these factors are hypothesized to be the potential causes for islet cell losses. In the present study, pressure and temperature data was collected with a remote data logger, and analyzed to determine the variations in pressure and temperature inside the shipping containers, while the containers were transported by both ground and air vehicles. Investigation of dissolved gases, and their variation inside the islet shipping containers, is a subject of future study. The physical components of the data acquisition system and an analysis of the experimental data are described in this thesis together with some conclusions about the potential causes of islet destruction



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CHAPTER I INTRODUCTION

Background

Type I Diabetes is a lifelong disease that develops when the pancreas produces too little or no insulin [4]. The pancreas consists of several million islet cells (organs) whose purpose is to make insulin in the right amount at the right time [2]. Islet cells were discovered in 1869 by the German researcher, Paul Langerhans [2]. These cells consist mostly of beta cells; cells which produce insulin. Islet cells have the ability to sense when blood sugar (glucose) levels are rising. When this happens, the islet cells allow the entrance into the pancreas of the chemical that activates insulin production. Insulin allows glucose to enter the cells of a human's body, where it is burned for energy. Without the insulin, glucose levels in a human's body will escalate to a life-threatening limit. At this point, damage can occur to blood vessels and nerves throughout a human body. Also associated with high glucose levels is the danger of eye, heart, and kidney disease.

Even though Type I Diabetes carries with it threatening health conditions, treatments are available to provide a long, healthy life to those affected by this disease. These treatments include eating a well balanced diet, taking insulin shots, and getting regular exercise [4]. Due to advancements in medical science, alternate treatment methods are being discovered. One form of alternate treatment is the transplantation of donated islet cells. Because of the delicate nature of the islet cells, transplantation can be a difficult procedure. The idea of transplantation is to remove healthy islets from a donor pancreas (from a person who has just died) and to place them in the body of a person with diabetes, where they begin to make insulin for that person [2].

The procedure for extracting human islet cells is laborious and requires the utmost precision. As shown in figure 1.1, the procedure consists of ten steps:

First, the pancreas is surgically removed from the human cadaver. Next, a bacterial collagenase enzyme, ex vivo, is injected into the duct of the pancreas and the organ is kept at 37°C in a specialized chamber.



-1-

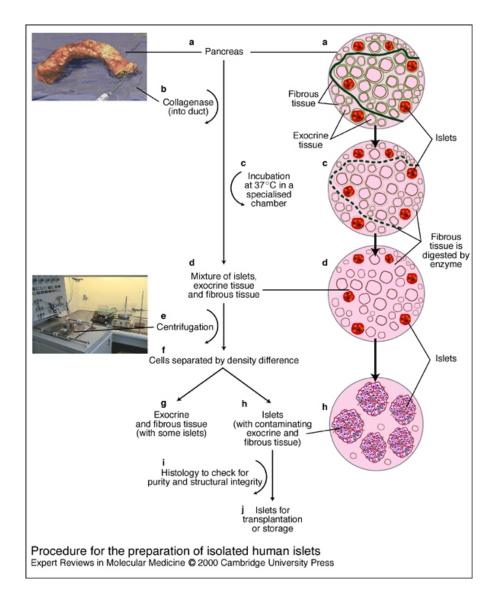


Figure 1.1 - Procedure for the Preparation of Isolated Human Islets



The collagen (fibrous) structure of the pancreas is then broken down by the enzyme. As a result, the islets are liberated, and are separated from the surrounding exocrine tissue using differential density centrifugation. Before use, islets can be identified by their uptake of a zinc-binding dye, and their structural integrity and purity are confirmed by histological examination. Islets can be used for transplantation immediately or stored at cold temperatures. [1]

Even though the transplant process seems beneficial and optimistic, there are still some problems that have not been solved. Due to injuries and damages sustained while being surgically removed, as well as the recipient patient's body rejecting the new cells, the transplant procedure has not been conducted on many people. The affects of antirejection medicine that must be taken by those patients (to keep them from rejecting the transplanted islets) could leave the patients in worse health. Also, there just aren't enough donor islets available: four donor pancreases are necessary to obtain enough islets for just one transplant patient [2].

None the less, the medical profession is seeking solutions to these problems. Just a few of the adjustments doctors are taking to make islet transplantation easier are using chemicals to make the surgical procedure gentler, enclosing islets in a coating or capsule for protection against rejection, and testing places, such as a kidney or a blood vessel, in a patient's body to hide the islets [2]. As for future transplants, doctors are looking into the idea of using created islet cells, cells that start out as a type of cell that is sound and abundant, which are then altered so they can produce insulin.

Problem Definition

The University of Tennessee at Memphis has a nationally known diabetes research center. One of the main tasks of this center is the removal of the islet cells from donated pancreas organs and shipment of them to recipient patients. After the researchers remove them, the islet cells are shipped in containers to different medical centers around the U.S. Although the removal of islet cells proves to be successful, a problem has been discovered in the islet shipping process.



Researchers at The University of Tennessee at Memphis have used two methods of shipping the islet cell containers. Samples destined for Nashville, and nearby destinations, are sent by automobile, where as the samples headed for distant locations are sent by airplane. Upon reaching their destination in Nashville, the islet cells have been conserved, that is, they maintain their numbers (a bottle count). Unfortunately, when the containers reach distant locations like California, the number of islet cells has been substantially decreased (the bottle count decreases). Travel times are roughly comparable, hence time of travel is not thought to be a reason for islet losses.

This investigation deals with an attempt to determine why pancreatic islet cells are destroyed by shipping them in commercial air carriers. The investigation will begin with a discussion of the potential factors in the environments of the cells being shipped that could be causing the number of islet cells to decrease during the flight to California. Potential factors include pressure, temperature, dissolved gas, radiation, acceleration, and flight duration. Of those factors, only two will be examined in this thesis: pressure changes and temperature fluctuations. It appeared from earlier preliminary data taken by Memphis that pressure and temperature inside the aircraft cabin were important factors. The presence of dissolved gas inside the shipping containers will be investigated in future research activities. A research program for carrying out an experimental investigation of the pressure and temperature factors is described and the results of this research are provided herein. Conclusions from the analysis of the experimental research are drawn and recommendations for avoiding islet destruction are presented.



CHAPTER II TEST APPARATUS

Data Acquisition System

In order to accomplish the research on islet destruction and to identify, if possible, the potential causes for the decline in the islet cell count, a data acquisition system had to be designed and built to survey and record the environment inside islet cell shipping containers. This device was designed to collect and store experimental data while tests were being run on the islet cell containers. The data would show pressure and temperature changes, as well as the presence of dissolved gases.

Initially, the device was designed to measure only temperature and pressure in the islet container. After careful study, it was decided that the device required a remote data logger to record the data from: two thermistors, one to measure ambient temperature and one to measure the temperature of the islet liquid; two pressure transducers, one to measure bottle pressure and one to measure the pressure of the surroundings; two dissolved gas probes, one for oxygen and one for carbon dioxide. In order for the data logger to be able to read the measurements of the thermistors, pressure transducers, and dissolved gas probes, a circuit was developed to convert voltage readouts to calibrated data points. The schematic for the data logger circuitry can be seen in Appendix A.

TFX-11 Remote Data Logger

A remote data logger was purchased from Onset Computer Corporation. The Tattletale Flash eXpress[®] data logger is ideal for embedded data acquisition applications. The logger, Figure 2.1, features portability, allows prolonged field deployment, fast sampling over multiple channels (eleven 12-bit analog and eight 8-bit analog channels), has small size (2.4" x 3.2" x 0.5") and weight (1.1 oz.), low power drain (100mA), non-volatile data storage, and 1 MB of Flash memory. TFBASIC[®] was the programming language provided by Onset Computer Corporation for use with the data logger. The program used to execute the islet experiments, as well as the user instructions, can be seen in Appendix B. The advantage of the reduced size and weight of the data logger eliminated the cost of designing new islet shipping



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Figure 2.1 - TFX-11 Remote Data Logger

containers. Also, due to the small weight difference between the research islet container and normal islet containers, cargo carriers will not be able to discern a difference between a test package and a normal package. This will ensure that actual real-time data will be collected..

Temperature Sensors

Thermistors were supplied by Onset Computer Corporation with the purchase of the TFX-11 data logger and were used as temperature sensors for the islet experiments. Because the TFX-11 data logger has a pre-defined temperature command, a calibration of the thermistors was not necessary. The TFX-11 manual provided a schematic for the thermistor circuit, as well as the parts needed to create the circuit. Once the circuit was placed on the breadboard of the data logger, the TEMP command converted the thermistor voltage output into degrees C. Using a 12-bit A/D converter provides about 0.03°C resolution for temperature ranges from 0°C to 35°C.



Pressure Transducers

Two stainless steel isolated pressure sensors were purchased from Invensys Sensor Systems for use with the data acquisition system. Because the pressure sensors are specifically designed for applications that can be exposed to a vacuum, tests could be executed in a vacuum chamber to simulate drop in pressure due to a change in altitude when flying. This proved beneficial in saving time and money in the research program. The pressure sensors had a range of 0-15 psia, a proof pressure¹ of 45 psia, and a burst pressure² of 75 psia. The steps taken in calibrating the pressure sensors are given in the next chapter.

Dissolved Gas Probes

The probes used in the islet experiments were purchased from Microelectrodes, Inc. The Dip-Type O_2 and CO_2 probes feature fast response times and small physical dimensions. The probes have body diameters of 6mm and tip diameters of 3mm. The lead wires of these probes run through a stainless steel isolation plug to the TFX-11 data logger and have a diameter of 1.5mm each.

Stainless Steel Isolation Plug

After cutting a $\frac{1}{2}$ " hole in the top of the islet container bottle cap, a 316 stainless steel plug was fabricated to serve as the isolation point between the environment of the islet cells and the surrounding environment. After machining the plug, five holes were drilled: two 0.005" holes for the thermistor, one 0.005" hole for the pressure transducer, with a 0.125" diameter, 0.400" deep recess for the copper pressure guiding tube, and two 0.0625" holes for the dissolved gas probes. A stainless steel fastening nut was machined to securely hold the plug in place. A groove was cut around the plug to house a rubber o-ring. This would ensure a tight seal between the plug and the bottle cap. Machine drawings for the stainless steel plug, as well as the complete test bottle set-up, can be seen in Appendix C.

²The maximum pressure that can be applied to a transducer without rupture of either the sensing element or transducer case.



¹The maximum pressure that can be applied without changing the transducer's performance or accuracy.

Shipping Container

The package used to transport the test apparatus, shown in Figures 2.2 and 2.3, was the same as used by the University of Tennessee at Memphis to transport pancreatic islet cells. The packaged was constructed of cardboard and Styrofoam with overall dimensions of 14" x 10.5" x 13.5". The container was packed by UT Memphis, in accordance with standards, for all tests originating from Memphis. For all other tests, the container was packaged close to Memphis standards.

Pressure Transducer Calibration

The pressure sensors required a calibration curve to change the A/D voltage output into pressure in units of inches of mercury, (in Hg). Of the various techniques for calibrating a pressure transducer, a barometer was chosen to provide the most accurate results.



Figure 2.2 - Shipping Container (Inside)





Figure 2.3 - Shipping Container (Outside)

Definition of a Barometer

The mercury barometer, Figure 2.4, is constructed by filling the tube with air-free mercury and inverting it with its open end beneath the mercury surface in the receptacle. The basic scheme is frequently used in industry for the direct measurement of any absolute pressure [3]. The end of each pressure transducer was attached to the barometer and the level of mercury was varied with a pump. A scale was equipped on the barometer to determine the pressure value (in Hg) of the corresponding mercury level. As the pressure changed, the TFX-11 data logger provided an output voltage.

Data Collection

As the pressure in the manometer changed, the TFX-11 data logger recorded corresponding values ranging from 0-65535. Table 2.1 shows the data collected for each of the pressure transducers.



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Figure 2.4 - Mercury Barometer

Data Analysis

Using the results from Table 2.1, a calibration curve was generated in MS Excel. This curve would provide an equation for converting the TFX-11 voltage readout into an inches of mercury pressure reading. The data reduction equation for the bottle pressure (transducer 1) can be seen in Equation 2.1, where \mathbf{x} is the voltage readout from the transducer.

$$\mathbf{y} = \mathbf{0.00056172x} - \mathbf{0.32283071} \tag{2.1}$$

The equation for the ambient pressure (transducer 2) is shown below in Equation 2.2, where, again, \mathbf{x} is the voltage readout from the .

$$y = 0.00056542x - 0.85560835 \tag{2.2}$$



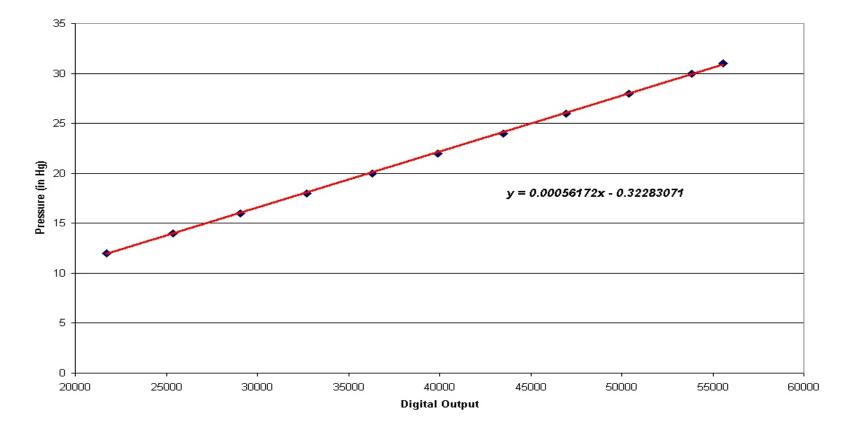
-10-

Manometer Setting (in Hg)	TFX-11 Readout Bottle Pressure Transducer (1)	TFX-11 Readout Ambient Pressure Transducer (2)
31	55568	56192
30	53824	54432
28	50384	50992
26	46960	47552
24	43520	44128
22	39920	40624
20	36304	37008
18	32688	33408
16	29056	29792
14	25392	26192
12	21744	22560

Table 2.1 - Calibration Data for Pressure Transducers

With the calibration procedure completed, the equations were entered into the TFBASIC program. The TFX-11 data logger had been properly calibrated to take accurate pressure readings in the bottle and of the surroundings. Figures 2.5 and 2.6 show the calibration curves for the bottle pressure transducer and the ambient pressure transducer, respectively.



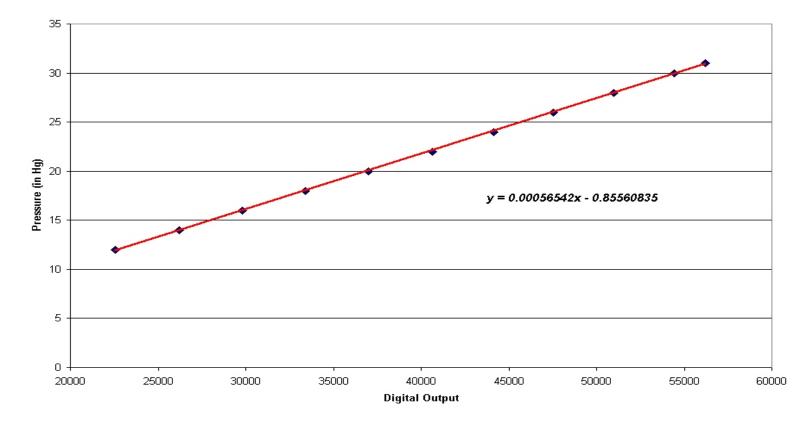


Calibration Curve - Bottle Top Pressure Transducer

Figure 2.5 – Bottle Pressure Transducer Calibration Curve



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Calibration Curve - Ambient Pressure Transducer

Figure 2.6 – Ambient Pressure Transducer Calibration Curve



CHAPTER III TEST RESULTS

Islet Container Bottle Tests

After completion of the calibration procedure for the pressure transducers, the first test executed was a pressure test on the islet cell containers. The University of Tennessee at Memphis provided fifteen islet cell bottles for use in the project's experiments. The purpose of the test was to determine if the islet bottles can maintain their internal pressure. At this stage, no alterations had been made to the bottle.

Islet Container Test Configuration

For this test, an instrumentation package, Figure 3.1, consisting of a pressure transducer and LCD readout, which fit entirely inside the islet bottle, was used to provide instantaneous pressure measurements. The schematic for the LCD display circuit can be seen in Appendix A.

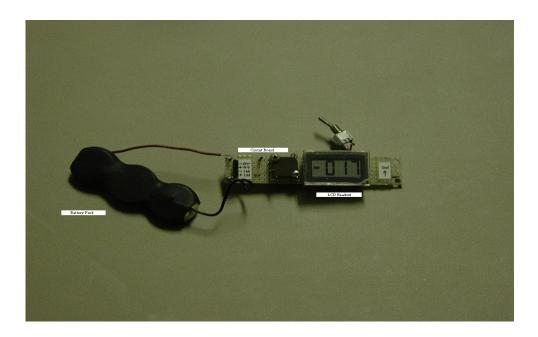


Figure 3.1 - Instrumentation Package



Next, the instrumentation was placed securely inside the bottle. In accordance with the format used by the University of Tennessee at Memphis, the islet bottle was fastened with the appropriate cap, and then wrapped with Parafilm to ensure a tight seal. The bottle was then placed inside a vacuum chamber and exposed to various pressure levels, from -10 in Hg to -24 in Hg. Figure 3.2 and 3.3 show the test set-up for the islet cells bottle.

Islet Container Data Analysis

As the pressure in the vacuum chamber changed, the LCD readout would display the corresponding pressure value inside the bottle. Several data points were collected over a wide range of pressure values for each of the fifteen test bottles. Once the data was collected, an Excel plot was generated for the test bottles. It was determined that four of the fifteen bottles, showed significant pressure loss. Figure 3.4 shows the data plot for the fifteen islet containers.



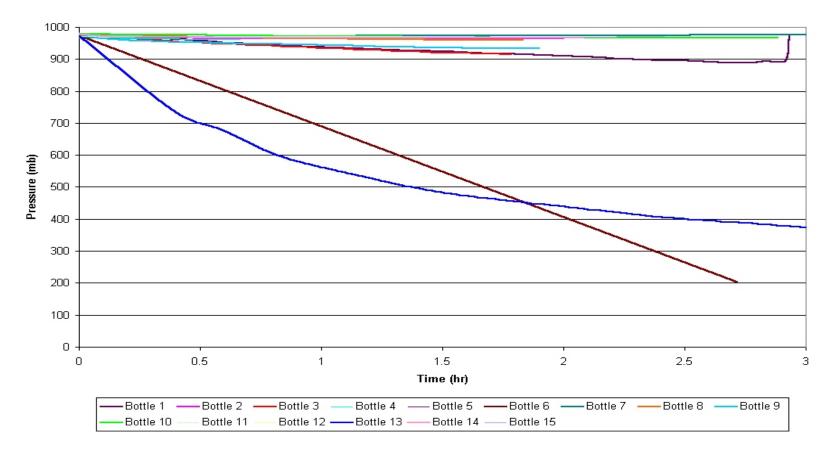
Figure 3.2 - Islet Bottle and Pressure Transducer





Figure 3.3 - Islet Bottle in Vacuum Chamber





Islet Bottle Pressure Tests

Figure 3.4 – Islet Container Test Results



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Islet Bottle Tests

Once the data acquisition system had been assembled, and initial laboratory experiments run to verify that the system was functioning properly, the first round of environmental testing was ready to begin. Three experiments were conducted on automobile trips and two were conducted in flight.

The University of Tennessee at Memphis places the islet cells in an electrolyte solution when transporting the bottles to Nashville and California. Because the islet electrolyte solution was not readily available, a salt water solution was created to serve as a test liquid for the automobile tests and the UTSI flight tests.

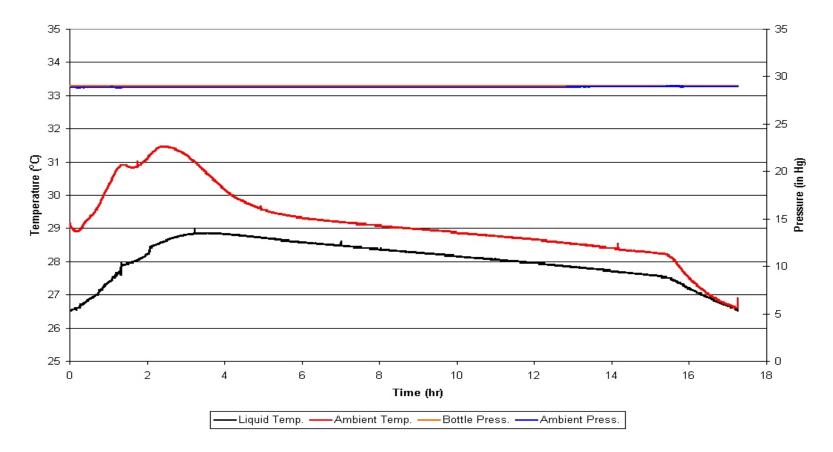
Automobile Tests

The tests were conducted over an extended period of time and subjected to changing climate conditions due to fluctuations in land elevation and atmospheric temperature as the trip progressed. Each of the tests originated from The University of Tennessee Space Institute (UTSI) which has an approximate elevation of 1000ft and ambient pressure of 28.86 in Hg. The experimental tests were run at elevations above and below the elevation of Tullahoma (UTSI).

The June 26, 2003 test was conducted over a time span of 17 hours. The trip to Huntsville, Alabama resulted in a drop of elevation from 1000ft to 650ft for a change in pressure of about 0.37 in Hg, overall. The June 27, 2003 test to Dyersburg, Tennessee and the July 8, 2003 test to South Pittsburg, Tennessee was conducted over a time span of 20 hours. The trip to Dyersburg resulted in an elevation drop from of 1000ft to 350ft(p = 0.69in Hg). The trip conducted to South Pittsburg passed over Monteagle mountain and down to South Pittsburg, resulting in an elevation change from 1000ft up to 2100ft (p = -1.0in Hg) back down to 625ft (p = 1.5in Hg).

Figures 3.5, 3.6, and 3.7 show the results of the three automobile tests. In the plots, the pressure changes are minimal and the temperature readings (the bottle and the surroundings) parallel each other. The bottle thermistor in the South Pittsburg trip failed. It was determined that one of the lead wires had malfunctioned.

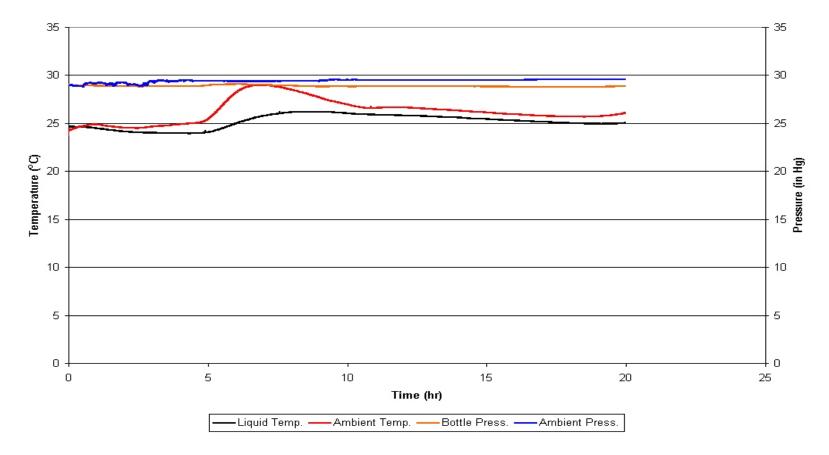




17- Hour Pressure Road Test (Salt Water) - June 26-27, 2003 - Tullahoma - Huntsville

Figure 3.5 – Tullahoma to Huntsville Automobile Test

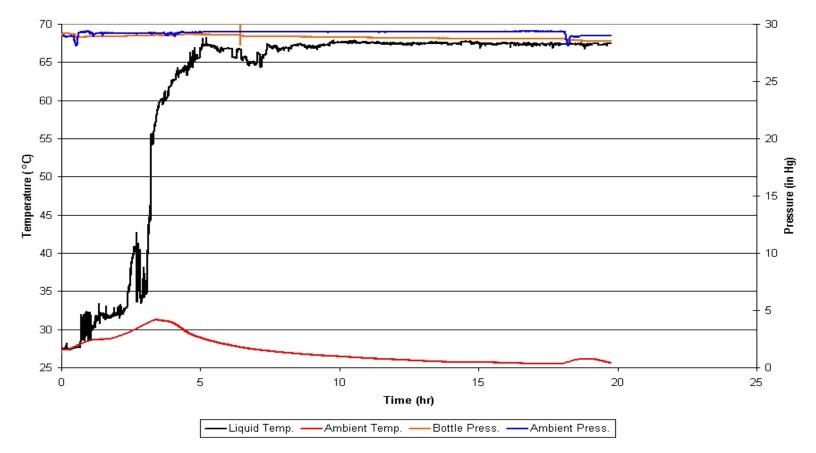




20-Hour Temperature Road Test (Salt Water) - June 27-28, 2003 - Tullahoma-Dyersburg

Figure 3.6 – Tullahoma to Dyersburg Automobile Test





Salt Water Temperature Test - July 8, 2003 (Tullahoma - South Pittsburg)

Figure 3.7 – Tullahoma to South Pittsburg Automobile Test



UTSI Flight Tests

The next series of tests were conducted to transport islet bottles by airplane. The first of these tests was needed to ensure that the test apparatus would work properly. The Aviation Systems Department at UTSI assisted the research team with the experiments by flying the package in one of the UTSI airplanes. The tests were conducted over the Tullahoma area (land elevation of 1100ft) at varying altitudes.

The first test was conducted by Mr. Kan-Wai Tong on May 12, 2003. The test container experienced an altitude change from 1100ft to 12,000ft (p = -9.72in Hg) and back down to 1100ft. For this test, there were two ascend/descend cycles. Figure 3.8 show the results of the first UTSI flight test. In the plot, the results show no significant changes in the islet bottles pressure, as well as no significant temperature fluctuations.

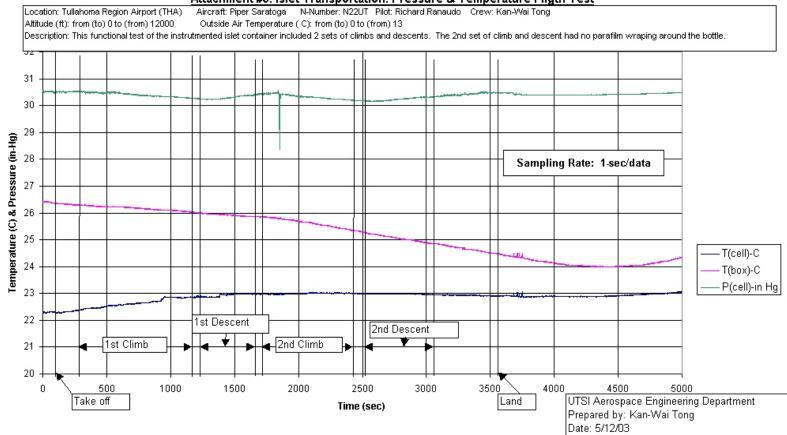
The second test was conducted on July 10, 2003. In this test, the islet container experienced a two cycle ascend/descend patterns from 1100ft to 9000ft (p = -7.35in Hg) and back down to 1100ft. Figure 3.9 shows the results of the second UTSI flight test. As the pressure of the environment changed did the pressure of the islet bottle. It was determined after the flight that the islet bottle's cap had a small crack around the edge. This crack was believed to be the reason that the pressure in the islet bottle was not held constant.

After replacing the damaged islet cap, the test apparatus was configured for its first real-time shipping test by commercial aircraft, since the test equipment proved that it would function properly during flight.

Commercial Aircraft Flight Tests

Two tests were conducted in real-time flight conditions that would be experienced by islet cell containers in regular commercial shipping processes. The airplane tests would expose the experimental islet container, filled with the electrolyte solution used by UT Memphis, to an aircraft cabin pressure during flight. Both tests originated from Memphis, Tennessee, but with different destinations.

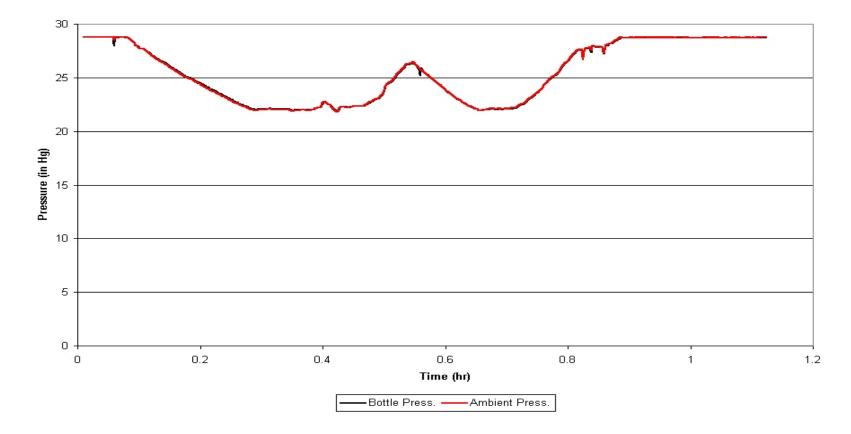




Attachment #3: Islet Transportation: Pressure & Temperature Fligth Test

Figure 3.8 - First UTSI Flight Test





Salt Water Pressure Flight Test - July 10, 2003

Figure 3.9 - Second UTSI Flight Test

المناركة للاستشارات

The first test was conducted from Memphis to Atlanta, Georgia, to Nashville, Tennessee, and then by automobile to UTSI. Figure 3.10 shows the results of the first flight test. In the plot, the results show that the experimental islet container maintained internal pressure during the flight from Memphis to Atlanta. However, during the flight from Atlanta to Nashville, the internal pressure leaked.

The second test was flown from Memphis to Los Angeles, California to Nashville and by automobile to UTSI. Figure 3.11 shows the results of the second flight test. In the plot, the results show that the experimental islet container failed to maintain internal pressure. Also, due to a delay at the airport in Los Angeles, the data logger ran out of memory before it could record data during the return trip. Upon the return of the package to UTSI, it was discovered that the top of the experimental islet container developed a crack around the edge, just like the crack discovered in the second UTSI flight test, causing the leak of pressure during flight. Also, the thermistor inside the experimental islet container experienced strange fluctuations in readings. After careful examination, the thermistor appeared to be functioning properly and the cause of the fluctuations was not positively identified.

The crack that was discovered after the second test could possibly have occurred during the first airplane test. After the first test, the crack was small enough to be missed by the naked eye. The additional pressure drop of the second test may have caused the bottle to expand and force the crack to increase in size.

Thermos Bottle Tests

After examining the results of the automobile and airplane tests conducted on the islet cell containers, which showed evidence of pressure leaks, it was decided that an alternate design for an islet shipping container should be investigated. The most accessible container that would be of use to the University of Tennessee at Memphis was a wide mouth thermos bottle.

Unfortunately, before the first thermos container test was conducted, a problem was discovered; the existing data logger would not fit inside the thermos bottle even with its wide mouth. The thermos



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Memphis to Atlanta to Nashville to Tullahoma Pressure and Temperature Test - July 21, 2003

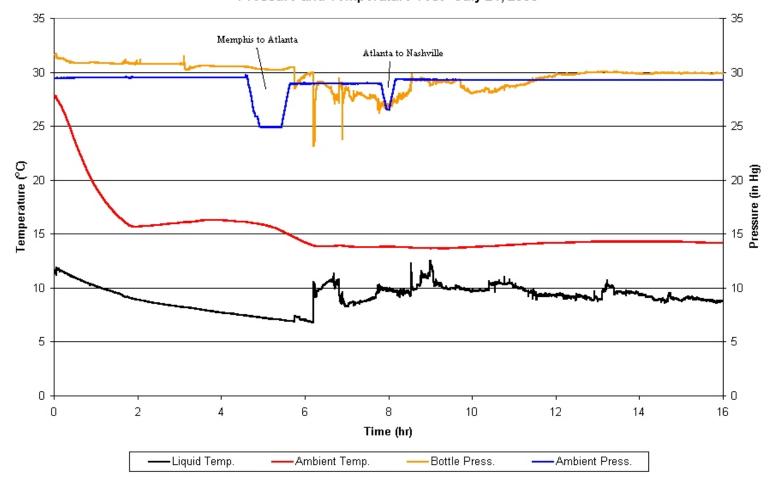
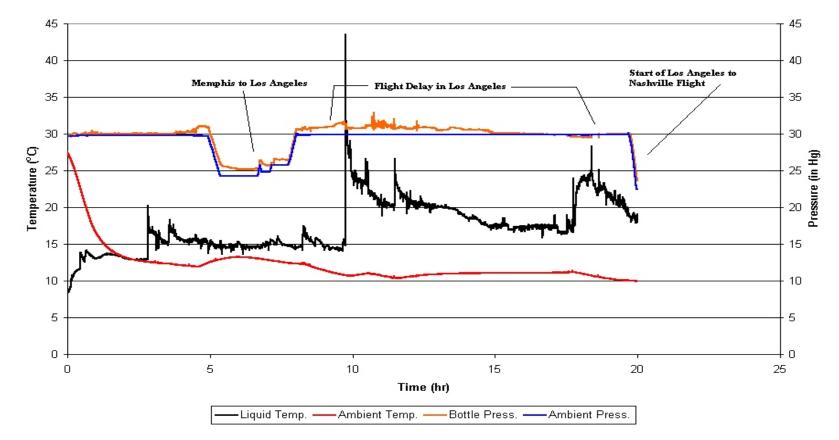


Figure 3.10 - Memphis to Tullahoma Flight Test





Memphis to Los Angeles to Nashville to Tullahoma Temperature and Pressure Test - July 27, 2003

Figure 3.11 - Memphis to Los Angeles Flight Test



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Figure 3.12 - Test Thermos

bottle, shown in Figure 3.12, measures 10" tall with a 4.75" outside diameter and a 2.875" inside diameter. The data logger and case measured 3.375" x 5.3125" x 1.5". Therefore, a new data logger and circuit board would need to be designed that would connect with the Tattletale TFX-11v2 controller board, a thermistor, and a pressure transducer to record pressure and temperature, as well as fit inside the thermos container without any modifications made to the thermos.

Circuit Board Design

The first step in developing the new circuit board was to design the hardware board using a software program called ExpressPCB^{\circ}. The program allows the user to determine the size of the board, the layout of required circuit components, and the path of the data lines that link the components. Once the circuit design was completed, the file was sent electronically to ExpressPCB^{\circ} where the design was etched onto a board. Next, the required components to make the new data logger work were ordered from Digi-Key^{\circ}.





Figure 3.13 - Thermos Data Logger

Once the circuit board and parts arrived, with the help of Mr. Mike Leigh, the components were soldered onto the board in the appropriate locations. The schematic for the circuit board can be seen in Appendix A. Next, the circuit had to be tested to ensure that every component was operating as required.

The troubleshooting phase produced a few adjustments that were required to make the data logger work properly. The new data logger was now fully operational, ready to record pressure and temperature changes inside the thermos bottle. The next step was calibrating the pressure transducer with the new data logger. Figure 3.13 shows the finished thermos data logger.

Thermos Container Flight Tests

To see if the thermos could be used as an alternate travel container for islet cells, four tests were conducted over a one-month span to determine if the thermos bottle would maintain temperature and pressure levels when subjected to varying environmental pressures. In addition, the original data logger was placed inside the shipping container along with the thermos bottle. This would ensure that the thermos



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bottle went through a variable pressure environment, as well as providing a basis of comparison to the changes taking place in the shipping container.

The first test was conducted December 1^{st} though the 2^{nd} of 2003. The air route taken by the container began in Memphis then went to Los Angeles, back to Chicago, and then to Nashville where it was then transported to UTSI by automobile. At that point, the program had exceeded its time limit and the data logger shut off. The total measured elapse time of the trip was twenty hours.

The second test was conducted December 12th through the 13th of 2003. The container was taken from UTSI to Nashville where it was flown to Los Angeles and back to Memphis. The total measured elapse time of the trip, when the program reached its stop point, was forty hours. The reason the data logger went an extended twenty hours over the first trip was that the time interval for sampling was changed from collecting data every five seconds to every ten seconds.

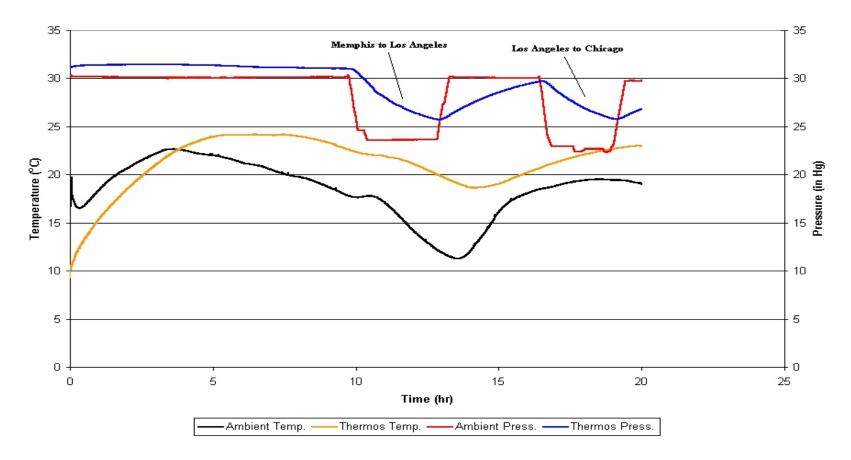
The third test was conducted December 15th through the 16th of 2003. The container was first driven to Memphis where it was flown to Nashville, then transported by automobile to UTSI. The total measured elapse time of the trip was twenty-two hours.

Finally, the last test was conducted January 5th through the 6th of 2004. The container went from Memphis to Los Angeles, from Los Angeles to Atlanta, from Atlanta to Nashville, then back to Tullahoma. The total measured elapsed time of the trip was 28 hours.

Figures 3.14, 3.15, 3.16, and 3.17 show the results of the four thermos bottle tests. It was found that the thermos bottle maintained pressure better than the islet container used by the University of Tennessee at Memphis. However, as can be seen in the results, the thermos had a small pressure leak. Also, the thermistor in the fourth test recorded strange fluctuations in the temperature of the surroundings. The thermistor was checked and proved to be functioning properly. Temperature fluctuations may have occurred with the climate changes across the country.



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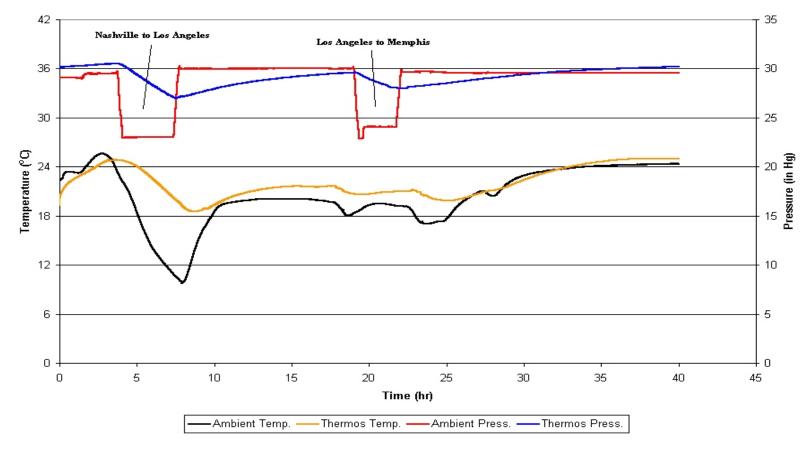


Thermos Test (Dec. 1-2, 2003) - Memphis-Los Angeles-Chicago

Figure 3.14 - First Thermos Flight Test



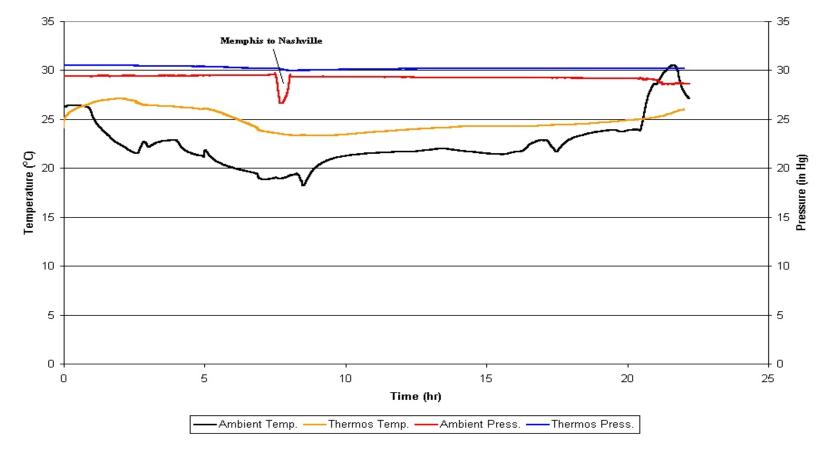
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Second Thermos Test - December 12, 2003 - Tullahoma - Los Angeles - Memphis

Figure 3.15 - Second Thermos Flight Test

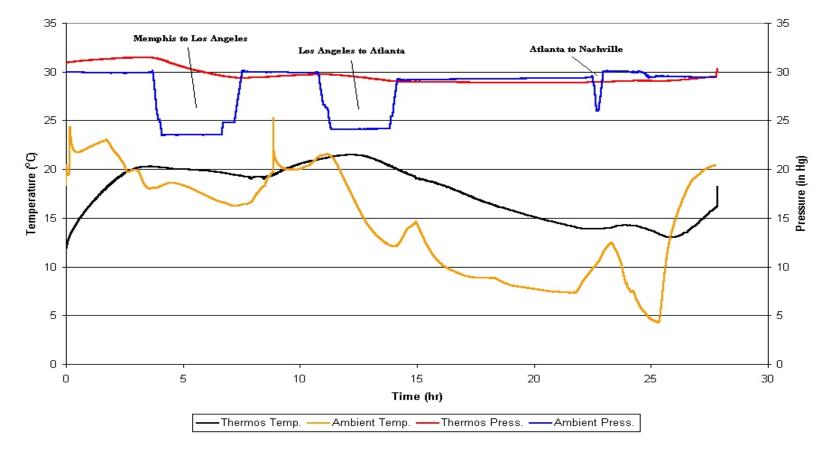




Third Thermos Test - December 15, 2003 - Memphis - Nashville - Tullahoma

Figure 3.16 - Third Thermos Flight Test





Fourth Thermos Test - January 5, 2004 - Memphis-Los Angeles-Atlanta-Nashville-Tullahoma

Figure 3.17 - Fourth Thermos Flight Test



CHAPTER IV CONCLUSIONS & RECOMMENDATIONS

Through vacuum chamber testing with islet bottles supplied by the University of Tennessee at Memphis, it was determined that the probability of the islet containers maintaining their pressure is about 70%. Experimental data also shows that the lowest environmental pressure subjected to the islet container is roughly 24 in Hg. This data verifies that the islet shipping container is placed in the cockpit of commercial aircraft, as required by the University of Tennessee at Memphis standards, and not in the cargo hold.

Furthermore, after several experiments were executed in an automobile and in an airplane, with the original islet container and a thermos container, collected data provided evidence as to the changes in pressure and temperature in the environment experienced by pancreatic islet cells. In the future, additional pressure and temperature tests will need to be executed on actual islet cells before a definitive ruling can be made on how pressure and temperature fluctuations effect the islet cell count. Also, testing of dissolved gases in the islet cells during transportation, which is currently underway, will be needed to determine environmental changes in dissolved oxygen and carbon dioxide in the blood substitute. Experimental testing of radiation during flight is another potential reduction factor on islet cells that could be examined.



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BIBLIOGRAPHY

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- [4] "Type I Diabetes." 30 May 2002. WebMD. 4 June 2003.
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APPENDICES



APPENDIX A

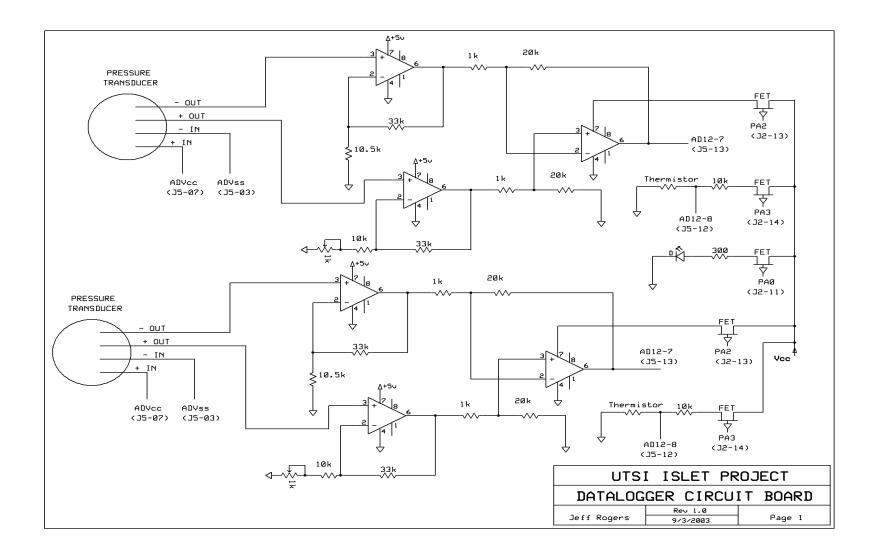
INSTRUMENTATION SCHEMATICS



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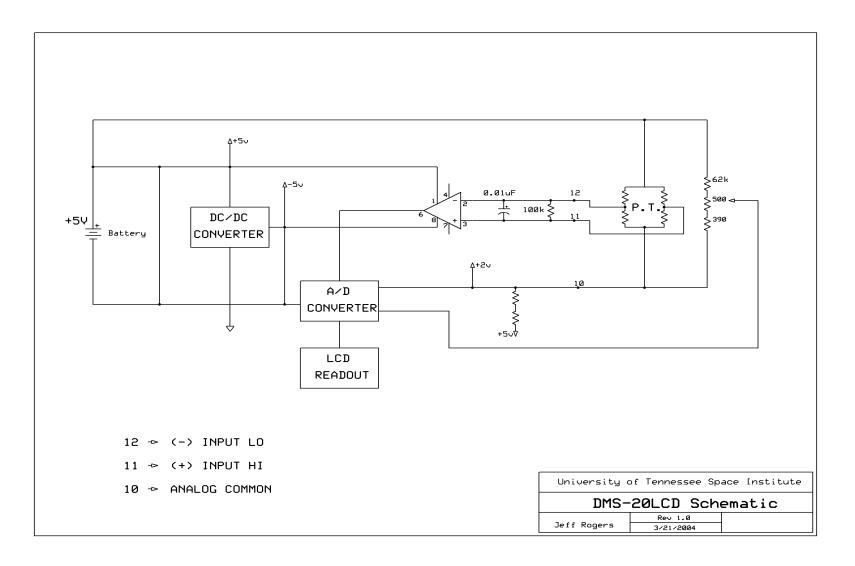
A1.	Data Logger Circuit Board	1
A2.	DMS-20LCD Schematic	-2
A3.	Thermos Circuit Board	3





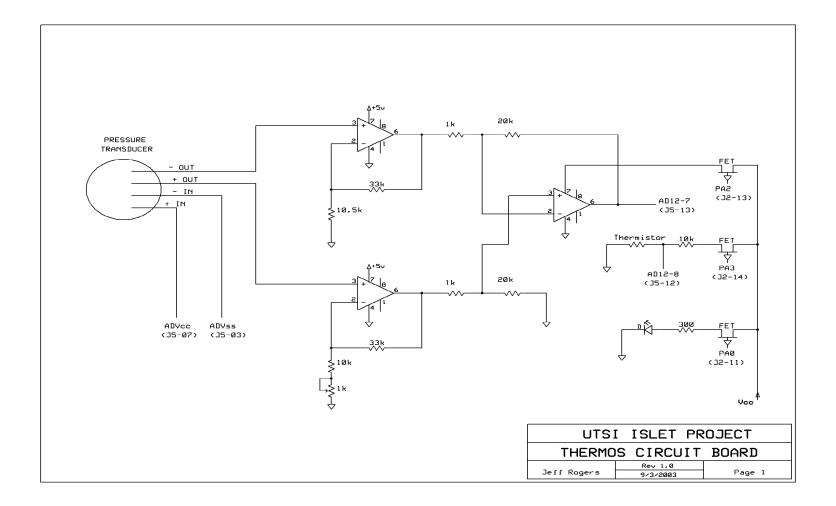


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APPENDIX B

TFBASIC® PROGRAMS



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B1.	TFX-11 V1 Data Logger Program	46
B2.	ThermosBottle Circuit Program	47
B3.	User Instructions	48



TFX-11 Data Logger Program

```
T(bottle)-C T(ambient)-C P(bottle)-in Hg P(ambient)-in Hg\n"
    print "
                   T(bottle)-C T(ambient)-C P(bottle)-in Hg P(ambient)-in Hg\n")
    store str("
    A = 0
Start: sleep 0
   A = A + 1
    if A > 7200
     stop
    else
     sleep 500 // 500 = 5 sec/data, 400 = 4 sec/data, 300 = 3 sec/data, 200 = 2 sec/data, 100 = 1 sec/data
     pclr 5,3,4,2,0
     tempc! = float(temp(chan(10)))/100
     tempa! = float(temp(chan(8)))/100
     pressb! = (((float(chan(9)))*0.00056172)-.32283071)
     pressa! = (((float(chan(7)))*0.00056542)-.85560835)
     BigStr$ = str(" (",#05,A,"): ",#7.2F,tempc!,#11.2F,tempa!,#14.2F,pressb!,#16.2F,pressa!,\13,\10)
     print BigStr$
     store #$,BigStr$
     pset 0
     Goto Start
    endif
```



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Thermos Bottle Circuit Program

```
T(bottle)-C P(bottle)-in Hg\n"
    print "
                   T(bottle)-C P(bottle)-in Hg\n")
    store str("
    A = 0
Start: sleep 0
    A = A + 1
    if A > 7200
      stop
    else
      sleep 500 // 500 = 5 sec/data, 400 = 4 sec/data, 300 = 3 sec/data, 200 = 2 sec/data, 100 = 1 sec/data
      pclr 5,3,4,2,0
      tempc! = float(temp(chan(10)))/100
      pressb! = (((float(chan(9)))*0.00056172)-.32283071)
      BigStr$ = str(" (",#05,A,"): ",#7.2F,tempc!,#14.2F,pressb!,\13,\10)
      print BigStr$
      store #$,BigStr$
      pset 0
      Goto Start
    endif
```



TFX-11 User Instructions

Start-Up

- 1. Turn on the Laptop. When the Windows Log-On Box appears, "Administrator" should appear in the user name box. Click the button marked "OK".
- 2. Install the serial and the parallel cable into their assigned slots in the back of the computer.

Uploading a Program

- 1. Double-Click the TFTools icon on the Desktop (Not the TFToolsv2 icon). This should start the TFTools program. A window labeled "TerminalForm" should pop up.
- 2. Plug the serial cable into the serial port on the TFX-11 Data Logger.
- 3. Turn on the Tattletale by flipping the switch towards the red dot. Look at the "TerminalForm" window on the laptop. If the program is running, press "Ctrl-C". This will end the program.
- 4. Plug in the parallel cable.
- 5. If there is data that you want to offload, go to the "Offloading Data" section. If not, proceed to step 5.
- 6. Click on the word "Tattletale" at the top of the TFTools program window. This will produce a drop down box with a list of commands. Click the command, "Load OS only". Once the OS is loaded, the "TerminalForm" window will provide the TFX-11 version information followed by the pound sign. If a problem arises, check the cable connections and start again. Otherwise, proceed.
- 7. Click on the word "File" at the top of the TFTools program window. This will produce a drop down box with a list of commands. Click "Open". This will allow you to select a program to open. The default should open up the folder labeled "Jeff-Islet". If not, the folder is located in the My Documents folder. You want to select the file labeled "Isletnotime.tfb".
- 8. The length of time the program will run can be changed by adjusting the number in the "if" command line. To determine the number to input, multiply the number of hours you want to run the program by 720.
- 9. Once the time is set, click the word "Tattletale" at the top of the program window, then click the command "Launch". This will load the program and begin testing. If you want to delay the start of the test, flip the power switch. Once you are ready to begin, just flip the switch back on. The program should start. If not, repeat all steps.



Offloading Data

- 1. Double-Click the TFTools icon on the Desktop (Not the TFToolsv2 icon). This should start the TFTools program. A window labeled "TerminalForm" should pop up.
- 2. Plug the serial cable into the serial port on the TFX-11 Data Logger.
- 3. Turn on the Tattletale by flipping the switch towards the red dot. Look at the "TerminalForm" window on the laptop. If the program is running, press "Ctrl-C". This will end the program.
- 4. Plug in the parallel cable.
- 5. Click the word "Tattletale" at the top of the TFTools program window, then click the command "Parallel off-load". A message box will appear asking you if you want to offload a "x" number of bytes of data. Click "OK".
- 6. Another box will appear asking you to save the file. Give the file a name and click "Save".
- 7. Once completed, the "TerminalForm" window will pop up. Press "Ctrl-C" to stop the program.
- 8. If you want to run another test, follow the steps in "Uploading a Program".



APPENDIX C

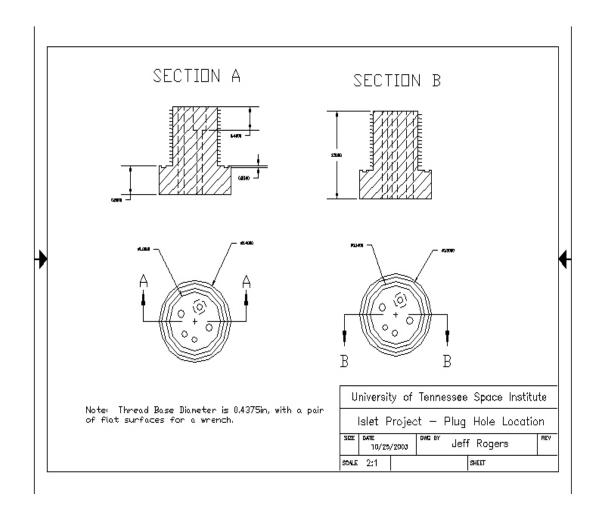
ISOLATION PLUG MACHINE DRAWINGS



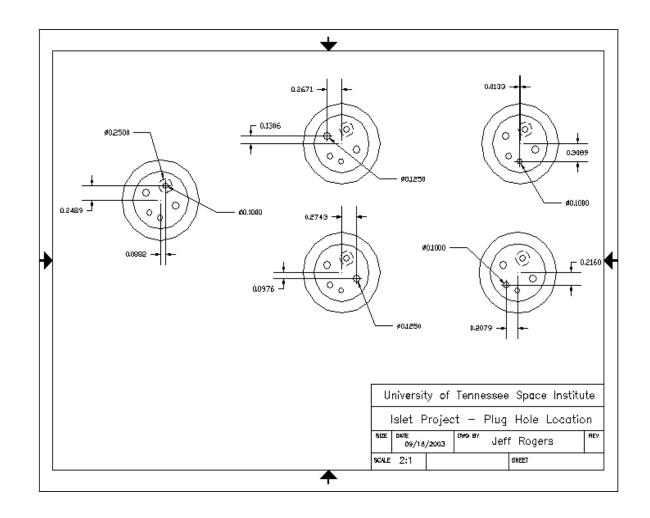
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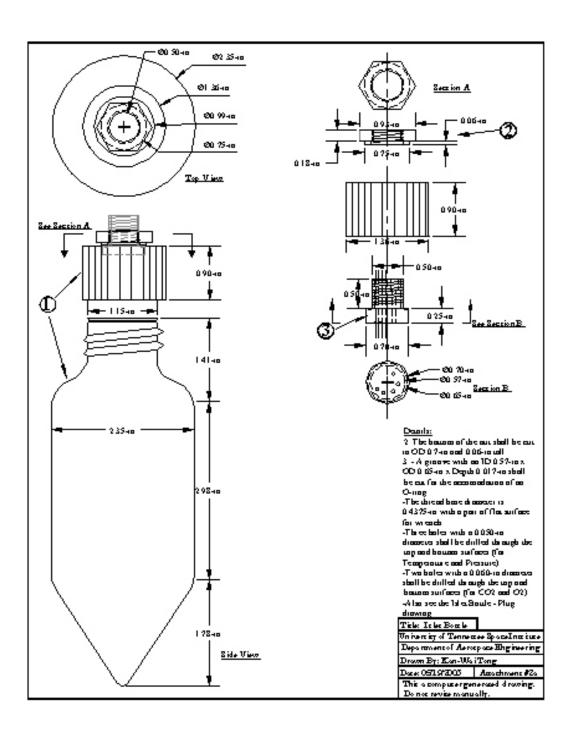








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VITA

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